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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/690,897 | 10/22/2003 | Mahavir Singh Khanna | RLL-297US | 6343 |
| 26815 | 7590 | 01/10/2006 | EXAMINER | |
| RANBAXY INC. 600 COLLEGE ROAD EAST SUITE 2100 PRINCETON, NJ 08540 | | | MORRIS, PATRICIA L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/690,897 | Applicant(s) KHANNA ET AL. | |
| | Examiner Patricia L. Morris | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-37 is/are pending in the application.
- 4a) Of the above claim(s) 17-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1625

DETAILED ACTION

Claims 1-15 are under consideration in this application.

Claims 17-37 remain held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restrictions

The restriction requirement is deemed sound and proper is hereby made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15 are rejected under 35 U.S.C. 102(a) and/or (e) as being anticipated by Sherman, Vijayaraghavan et al, Kamiyama et al. and Gustavsson et al. for the reasons set forth in the previous Office action.

Again, Sherman, Vijayaraghavan et al., and Kamiyama et al. specifically recite the instant compounds.I. Note, for example, Sherman et al. disclose the amorphous racemate omeprazole magnesium form, whereas Vijayaraghavan et al. disclose amorphous forms of omeprazole. Note section [0010] of Vijayaraghavan et al. Kamiyama et al. disclose the amorphous form of the R-enantiomer in example 4 therein. Gustavsson et al. specifically includes amorphous forms of the

Art Unit: 1625

sodium salt of the racemate. Note column 2, lines 28-32, therein. Hence, the instant compounds are deemed to be anticipated therefrom.

Contra to applicants' arguments in the instant response, amorphous esomeprazole salts are merely the S-isomers of omeprazole. The racemate consists of the R- and S-isomers. A novel chemical product is identified first by its "chemical nature". i.e., elemental and atom content. It is well known that the racemate consists of two enantiomers. Where a reference describes a sufficiently limited genus of a number of compounds closely related to another in structure, the reference may be said to provide a description of those compounds just as if they were identified in the reference by name. In re Schaumann, 572 F.2d 312, 197 USPQ 5 (CCPA 1978). Accordingly, in the instant case, since the formula has one asymmetric carbons is taught, one merely has to select from two enantiomers to arrive at the claimed invention.

The factual situation here is well within the "Petering doctrine": In re Petering et al., 49 CCPA 993, 301 F.2d 676, 133 USPQ 275 (1962). There the court affirmed a 102(b) rejection on the ground that the prior art, while it did not expressly name applicants' claimed compounds, did describe such a limited class of only twenty compounds "that one skilled in this art would at once envisage each member of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class as we have done here" (133 USPQ at 280). Here we do not have anywhere near twenty possible compounds within the limited class described by the references.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Sherman, Vijayaraghavan et al., Kamiyama et al. and Gustavsson et al. in view of Bohlin et al. and Broeckx et al. for the reasons set forth in the previous Office action.

As discussed supra, the references disclose the instant compounds. All the references disclose that the instant compounds exist in a solid form. Gustavsson et al. specifically recites that amorphous forms are included. Note column 2, lines 28-32. Further, Bohlin et al. disclose that it is well known in the art that S-omeprazole exists in amorphous, partly crystalline or substantially crystalline forms. Note column 1, lines 58-60, therein. Bohlin et al. and Broeckx et al. teach that omeprazole is a racemic mixture that consists of two single enantiomers. Hence,

Art Unit: 1625

the claimed isomer as well as its relative selectivity of properties *vis-à-vis* the racemate are suggested by the references.

Applicants do not point to any objective evidence which demonstrates that the claimed compounds as a class exhibit any properties which are actually different from the closest prior compounds embraced by Muller et al. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977); In re Hoch, 428 F.2d 1341, 166 USPQ 406 (CCPA 1970).

Claim Rejections - 35 USC § 112

The rejection under 35 USC 112 is withdrawn in view of applicants' amendments to the claims.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

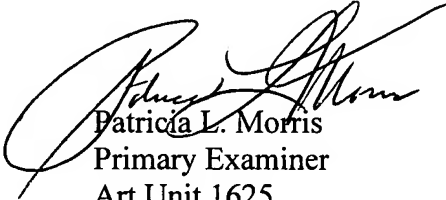
Art Unit: 1625

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688.

The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris
Primary Examiner
Art Unit 1625

plm
January 9, 2006